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UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

JOLENE GENTLEMAN,	)	**Civil Action No.:**
	)	
	)	
Plaintiff,	)	
	)	**COMPLAINT AND JURY TRIAL**
v.	)	**DEMANDED**
	)	
	)	
DAVOL INC., and	)	
C.R. BARD,	)	
	)	
	)	
Defendants.	)	
	)	

ORIGINAL COMPLAINT

Plaintiff JOLENE GENTLEMAN, by and through her undersigned counsel, brings this Complaint for damages against Defendants Davol Inc., and C.R. Bard, and in support states the following:

1. This is an action brought on behalf of Plaintiff JOLENE GENTLEMAN, arising out of the failure of Defendants' hernia mesh product, Ventralex ST Mesh. As a result, Plaintiff has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. At all material times Plaintiff has been a citizen and resident of Alaska and the United States.

3. Davol, Inc. ("Davol") is incorporated in Delaware, with its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices. Such devices include hernia meshes composed of polypropylene, and polyglycolic acid (PGA) fibers coated with Sepra Technology (ST), a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel.

4. C.R. Bard, Inc. ("Bard") is Davol's corporate parent/stockholder. Bard is incorporated and based in New Jersey. It is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices, and controls the largest share of the hernia mesh market. Bard participates in the manufacture and distribution of the Ventralex ST Mesh. It also manufactures and supplies Davol with material that forms part of the product.

5. At all material times Bard was responsible for Davol's actions, and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to the Ventralex ST Mesh sold in the United States. In such capacity, Bard committed, or

allowed to be committed, tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiff JOLENE GENTLEMAN to suffer injury and damages.

6. Defendants are individually and jointly and severally liable to Plaintiff JOLENE GENTLEMAN for damages she suffered, arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective Ventralex ST Mesh, effectuated directly and indirectly through their agents, servants, employees and/or owners, all acting within the course and scope of their agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all material times acting on behalf of Defendants and within the scope of their employment or agency.

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiff JOLENE GENTLEMAN and Defendants. The amount in controversy exceeds $75,000.

9. This Court has personal jurisdiction over each Defendant pursuant to the Alaska Long-Arm Statute, Alaska Stat. § 09.05.015. Defendants transact business within the State of Alaska, and contracted to sell and supply their Ventralex ST Mesh product in the State of Alaska. Defendants employ sales representatives in the State of Alaska to sell their products throughout the State, including the Ventralex ST Mesh implanted in Plaintiff JOLENE GENTLEMAN in Alaska. Defendants' tortious acts and omissions in the State of Alaska caused injury to Plaintiff.

10. Defendants have purposefully engaged in Alaska in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the Ventralex ST Mesh, for which they derived significant and regular income. Defendants intended and reasonably expected that that their defective mesh products, including the Ventralex ST Mesh, would be sold and implanted in Alaska and could cause injury in Alaska.

11. C.R. Bard is registered to transact business in Alaska.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

FACTS COMMON TO ALL COUNTS

13. On or about September 9, 2015, Plaintiff JOLENE GENTLEMAN underwent repair of Epigastric Incisional hernia by Dr. Danny Robinette at Fairbanks Memorial Hospital in Fairbanks, AK. A Ventralex ST Mesh patch 3.2 inch, Cat No. 5950009, Lot No. HUYL0495 was implanted in Plaintiff during this repair.

14. Defendants manufactured, sold, and/or distributed the Ventralex ST Mesh to Plaintiff, through her physician, to be used for treatment of hernia repair.

15. On or about August 11, 2016 , Plaintiff JOLENE GENTLEMAN underwent surgery by Dr. Dante Conley to explant the hernia mesh. During the surgery, the Plaintiff's hernia mesh was found to have folded over.

16. Plaintiff continues to experience complications related to the Ventralex ST Mesh. She will likely require additional surgeries to repair the damage from Defendants' product.

17. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of the Ventralex ST Mesh, including providing the warnings and instructions concerning their product.

18. Among the intended purposes for which Defendants designed, manufactured and sold the product was its use by surgeons for hernia repair surgeries. That was the purpose for which the Ventralex ST Mesh was implanted in Plaintiff JOLENE GENTLEMAN.

19. Defendants represented to Plaintiff and her physician that the Ventralex ST Mesh was a safe and effective product for hernia repair.

FDA 510(k) CLEARANCE PROCESS

20. The "510(k) clearance process" of the U.S. Food & Drug Administration (FDA) refers to Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA). Under this process, medical device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976 (when the MDA was enacted).

21. No clinical testing or clinical study is required to gain FDA approval under this process. Instead, a given device was supposed to demonstrate substantial equivalence to a predicate medical device.

22. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

23. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices the FDA had approved for sale pre-1976 could be sold to patients in a matter of 90 days—without any clinical testing.

24. Therefore, clearance for sale under the 510(k) process does not equate to FDA approval of the cleared medical device.

25. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

26. The NIH explained: "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to 1976 "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

27. Defendants cleared their Ventralex ST Mesh, and its related components, under the 510(k) Premarket Notification.

28. On June 18, 2002, the FDA issued a document entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26-page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a Class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

29. Due to Defendants' acts of fraudulent concealment, they are estopped from relying on any statutes of limitations or repose. Such acts include Defendants' intentional concealment from Plaintiff JOLENE GENTLEMAN and the general public that the Ventralex ST Mesh is defective, while continuing to market the product with the adverse effects described in this Complaint.

30. Given Defendants' affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known the Ventralex ST Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

31. Plaintiff incorporates by reference the allegations in all prior paragraphs.

32. Defendants expected and intended their Ventralex ST Mesh to reach users such as Plaintiff in the condition in which the product was sold.

33. The implantation in Plaintiff JOLENE GENTLEMAN'S body of the Ventralex ST Mesh was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

34. When the Ventralex ST Mesh was implanted in Plaintiff's body, the product was defectively manufactured.

35. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Ventralex ST Mesh implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

36. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished Ventralex ST Mesh product, which deviated from their material and supply specifications.

37. As a direct and proximate result of Defendants' defective manufacture of the Ventralex ST Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

38. Plaintiff incorporates by reference the allegations in all prior paragraphs.

39. Defendants' Ventralex ST Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the product, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

40. When affixed to the body's tissue, the impermeable coating of the ST Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

41. The ST coating provides an ideal bacteria breeding ground in which bacteria cannot be eliminated by the body's immune response, thus allowing infection to proliferate.

42. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ST Mesh. Although ETO is an effective disinfectant, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores if ETO is used. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores.

43. The ST Mesh, containing spores, will eventually cause an infection after implantation. The spores can remain dormant for extended periods of time, resulting in infections months or years after ST Mesh was implanted. The following literature discusses the necessity of moisture during ETO sterilization:

A. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**

Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

44. Defendants' Ventralex ST Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), and resulting in the inability to properly validate sterilization.

45. The coating on Defendants' product is cytotoxic, immunogenic, and non-biocompatible, causing or contributing to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

46. The ST coating is designed and intended to resorb in less than 30 days.

47. When the ST coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and polyglycolic acid (PGA) are exposed to the adjoining tissue and viscera. The mesh can thus become adhered to organs and cause incarceration of organs, and fistula formation.

48. The solid, flat, relatively smooth and continuous surface of Defendants' Ventralex ST Mesh inhibits the body's ability to clear toxins.

49. These manufacturing and design defects associated with the Ventralex ST Mesh were directly and proximately related to the injuries Plaintiff JOLENE GENTLEMAN suffered.

50. Neither Plaintiff nor her implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of Ventralex ST Mesh. Moreover, neither Plaintiff nor her implanting physician was adequately warned or informed by Defendants of the risks associated with the product.

51. The Ventralex ST Mesh implanted in Plaintiff failed to reasonably perform as intended. The product caused serious injury and had to be surgically removed via invasive surgery,

necessitating additional invasive surgery to repair the hernia that the product had initially been implanted to treat.

52. When the Ventralex ST Mesh was implanted in Plaintiff's body, it was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

53. Defendants expected and intended the Ventralex ST Mesh to reach users such as Plaintiff in the condition in which the product was sold.

54. The implantation of the product in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold it.

55. The risks of Defendants' Ventralex ST Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating—which is not used in any other hernia mesh product sold in the United States—incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ST coating leads to seroma formation, and provides a breeding ground for infection by protecting bacteria from being eliminated through the body's natural immune response. This ST coating also causes immunogenic responses, and was known to be cytotoxic.

56. The coating of the Ventralex ST Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and

intended to degrade over time inside the body. Thus, the coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues. Once exposed to the viscera, the polypropylene and PGA will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

57. The polypropylene mesh within the defective coating of the Ventralex ST Mesh was in itself dangerous and defective, particularly when used in the product in the manner intended by Defendants. The particular polypropylene material used in their product was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the ST coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the Ventralex ST Mesh, it is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

58. The appropriate treatment for complications associated with the Ventralex ST Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

59. Defendants' product was designed and intended for intraperitoneal implantation, which required it to be placed in contact with internal organs, thus unnecessarily increasing the risks of adhesion, erosion, fistula formation, and other injuries.

60. When the Ventralex ST Mesh was implanted in Plaintiff JOLENE GENTLEMAN, there were safer feasible alternative designs for hernia mesh products, including a flat, non-coated, single-layer mesh placed away from the bowel.

61. The Ventralex ST Mesh product costs significantly more than competitive products due to its unique ST coating, even though the ST coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

62. Defendants' Ventralex ST Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices utilizing this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

A. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not at present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

B. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in

humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**

Surgical Implants and Other Foreign Bodies. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

63. Plaintiff JOLENE GENTLEMAN was implanted with Defendants' Ventralex ST Mesh product, which also includes an inner ring of polydioxanone (PDO ring), to aid in the memory and stability of the device. The inner PDO ring is called SorbaFlex Memory Technology.

64. Once implanted, the PDO ring breaks down via hydrolysis over a period of at least 6 to 8 months. The PDO ring elicits an intense inflammatory response during absorption.

65. The Ventralex ST Mesh is vulnerable to buckling, folding, and/or migrating once the PDO ring has absorbed.

66. Defendants secure the ST coating to the polypropylene base of the mesh by suturing two circular rings of PGA. The two securing circular rings of PGA are not ST coated and are the closest part of the mesh to underlying organs once implanted. This results in significant amounts of bare PGA being exposed to underlying organs at the time of implantation.

67. The two circular rings of PGA securing the ST coating to the polypropylene have a tendency to come unstitched, resulting in segments of PGA protruding toward the underlying organs.

68. The method by which Defendants secure the ST coating to the polypropylene base of the mesh does not provide adequate or uniform coverage to the outer aspects of the base polypropylene from the time of implantation.

69. The securing circular rings of PGA do not extend to the outer aspects of the polypropylene base, which can result in the ST coating folding upon itself and exposing bare polypropylene.

70. The positioning/securing strap of the Ventralex ST Mesh is bare polypropylene without an ST coating.

71. The Instructions for Use for the Ventralex ST Mesh direct the implanting surgeon to secure it with tacks or sutures through the polypropylene positioning straps.

72. The polypropylene positioning straps have a tendency to tear at the base of the Ventralex ST Mesh after implantation, resulting in mesh migration and other injuries.

73. The polypropylene positioning straps have a tendency to tear where tacked or sutured, resulting in mesh migration and other injuries.

74. The polypropylene portion of the Ventralex ST Mesh has a tendency to unravel, creating a sharp "fishing line" effect, which can slice through the patient's tissue.

75. The additional layers utilized to create the patch of the Ventralex ST Mesh increase the intensity and duration of inflammation and foreign body response.

76. The Ventralex ST Mesh implanted in Plaintiff JOLENE GENTLEMAN failed to reasonably perform as intended. The product therefore had to be surgically removed necessitating further invasive surgery to repair the very issue that the Ventralex ST Mesh was intended to repair. The product thus provided no benefit to Plaintiff.

77. As a direct and proximate result of the product's defective and unreasonably dangerous condition, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

78. Plaintiff incorporates by reference the allegations in all prior paragraphs.

79. When the Ventralex ST Mesh was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. As described above, there was an unreasonable risk the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

80. Defendants expected and intended the Ventralex ST Mesh to reach users such as Plaintiff in the condition in which the product was sold.

81. Plaintiff JOLENE GENTLEMAN and Plaintiff's physicians were unaware of the defects and dangers of Ventralex ST Mesh, and were unaware of the frequency, severity and duration of the risks associated with the product.

82. Defendants' Instructions for Use provided with the Ventralex ST Mesh expressly understate and misstate the risks known to be associated specifically with the product, representing the associated complications such as inflammation merely as "possible complications." But the Ventralex ST Mesh will always incite severe inflammation once implanted. The inflammation caused by the Ventralex ST Mesh is chronic in nature and systemic, not acute localized inflammation.

83. No other surgical mesh sold in the United States has the dangerous and defective ST coating, which itself causes or increases the risks of numerous complications, including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to

physicians about the risks or increased risks specifically associated with the unique design of the Ventralex ST Mesh.

84. Defendants' Instructions for Use for the product also failed to adequately warn Plaintiff's physician of numerous risks that Defendants knew or should have known were associated with the Ventralex ST Mesh, including the risks of immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

85. Defendants failed to adequately warn Plaintiff or her physician about the necessity for invasive surgical intervention in the event of complications and failed to train the physician how to properly treat such complications when they occurred.

86. Defendants failed to adequately warn Plaintiff or her physician that the surgical removal of the Ventralex ST Mesh in the event of complications would leave the hernia unrepaired and much larger than the original; and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

87. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions; expressly intended for the ST Mesh to be implanted in contact with the bowel and internal organs; and marketed and promoted the Ventralex ST Mesh for that purpose. Defendants failed to warn physicians that the ST coating was temporary, and therefore at best would provide only a temporary adhesion barrier. Further, Defendants did not warn physicians that when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

88. Defendants failed to warn Plaintiff and her physician that the FDA considered the Ventralex ST Mesh device a significant risk.

89. Defendants marketed and continue to market the Ventralex ST Mesh in brochures and online without disclosing or making evident that PGA is utilized in the product.

90. With respect to the complications listed in the Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Ventralex ST Mesh were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

91. If Plaintiff and/or her physician had been properly warned of the defects and dangers of the Ventralex ST Mesh, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow it to be implanted, and Plaintiff's physician would not have implanted the product in Plaintiff.

92. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

93. Plaintiff incorporates by reference the allegations in all prior paragraphs.

94. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Ventralex ST Mesh, they failed to do so.

95. Defendants knew, or in the exercise of reasonable care should have known, that their product was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants knew

or should have known that Plaintiff and her physician were unaware of the dangers and defects inherent in the Ventralex ST Mesh.

96. Defendants knew or should have known that the polypropylene used to manufacture their product prohibited permanently implanting polypropylene into the human body.

97. Defendants utilized non-medical grade polypropylene.

98. Defendants knew or should have known that polypropylene is not inert and will degrade, flake, chip, and disperse throughout the body once implanted.

99. Defendants knew or should have known that polypropylene induces a severe inflammatory response once implanted, and continues to induce a severe inflammatory response indefinitely or until removed.

100. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

101. Defendants knew or should have known that PGA (polyglycolic acid) induces an intense local inflammatory response following implantation.

102. Defendants knew or should have known that carboxymethylcellulose induces an intense local inflammatory response following implantation.

103. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the Ventralex ST Mesh before introducing it into the stream of commerce.

104. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written

instructions and warnings for the Ventralex ST Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

105. Plaintiff incorporates by reference the allegations in all prior paragraphs.

106. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Ventralex ST Mesh.

107. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner than Plaintiff and his implanting physician in fact used it; and Defendants impliedly warranted that the product and is component parts was of merchantable quality, safe and fit for such use, and adequately tested.

108. Defendants were aware that consumers, including Plaintiff and her physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Ventralex ST Mesh.

109. Defendants'' Ventralex ST Mesh was expected to reach, and did in fact reach consumers, including Plaintiff and his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

110. Defendants breached various implied warranties with respect to Ventralex ST Mesh, including the following:

A. Defendants represented to Plaintiff and his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was save. But at

the same time they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

B. Defendants represented to Plaintiff and his physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and his physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time they fraudulently concealed information regarding the true efficacy of the Ventralex ST Mesh.

111. In reliance upon Defendants' implied warranties, Plaintiff, individually, and/or by and through his physician, used the Ventralex ST Mesh as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

112. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

113. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

114. Plaintiff incorporates by reference the allegations in all prior paragraphs.

115. Defendants negligently manufactured, designed, developed, tested, labeled, marketed and sold the Ventralex ST Mesh to Plaintiff.

116. On multiple occasions Defendants negligently concealed the harmful effects of the product from Plaintiff individually, and/or her physician. They continue to do so to this day.

117. On multiple occasions Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Ventralex ST Mesh to Plaintiff individually, and/or her physician. They continue to do so to this day.

118. Plaintiff was directly impacted by Defendants' negligence, in that she has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the product manufactured, sold and distributed by Defendants.

119. After Plaintiff sustained emotional distress, severe physical injuries, and economic loss, Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff and/or her physician.

120. Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff individually, and/or her physician, knowing that doing so would cause Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

121. As a proximate result of Defendants' conduct, Plaintiff has been injured. He has sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

JURY TRIAL DEMANDED

COUNT VII: FRAUDULENT CONCEALMENT

122. Plaintiff incorporates by reference the allegations in all prior paragraphs.

123. At all material times it was known or knowable to Defendants that their product caused large numbers of complications. It also was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with the Ventralex ST Mesh. It was known or knowable to Defendants that the safety and efficacy of their product had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. And it was known or knowable to Defendants that the product was not safe and effective. Defendants continued nonetheless to represent that their product was safe and effective.

124. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their product, Defendants failed to disclose this information to Plaintiff, her physician, and/or public at large.

125. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and her physician the true facts concerning their product, *i.e.*, that the Ventralex ST Mesh was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and was likely to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff JOLENE GENTLEMAN was implanted with Defendants' product.

126. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the product because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the Ventralex ST Mesh;

B. Defendants knowingly made false claims about the safety and quality of the product in documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of their product from Plaintiff.

127. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use Defendants' product.

128. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and her physician, with the intent to defraud them.

129. Defendants intentionally concealed or failed to disclose the true defective nature of the Ventralex ST Mesh, so that Plaintiff would request and purchase it, and healthcare providers would dispense, prescribe, and recommend it. And Plaintiff justifiably acted or relied upon the concealed or non-disclosed facts to her detriment.

130. At all material times, neither Plaintiff nor her physician was aware of the facts above. Had they been aware of those facts, they would not have acted as they did, *i.e.*, by reasonably relying upon Defendants' representations of safety and efficacy, and by utilizing Defendants' product. Defendants' failure to disclose this information was a substantial factor in the selection by Plaintiff's physician of Defendants' product. Defendants' failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

131. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

132. Plaintiff incorporates by reference the allegations in all prior paragraphs.

133. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Ventralex ST Mesh had not been adequately tested and found to be a safe and effective treatment. Defendants breached that duty as their representations were false.

134. Defendants failed to exercise ordinary care in the representations concerning their product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because they negligently misrepresented the Ventralex ST Mesh's high risk of unreasonable and dangerous adverse side effects.

135. Defendants also breached their duty in representing to Plaintiff, her physician, and the medical community that their product had no serious side effects different from older generations of similar products and/or procedures.

136. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or had reason to know, that the Ventralex ST Mesh had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

137. As a direct and proximate result of Defendants' conduct, Plaintiff JOLENE GENTLEMAN has been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

PUNITIVE DAMAGES

138. Plaintiff incorporates by reference the allegations in all prior paragraphs.

139. Defendants failed to adequately test and study the Ventralex ST Mesh to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation. Further, Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

140. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Ventralex ST Mesh, they developed, designed and sold the Ventralex ST Mesh, and continue to do so, because the product has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective product, including the risk of failure and serious injury, such as suffered by Plaintiff.

141. At all material times, Defendants knew or should have known that Ventralex ST Mesh was inherently more dangerous with respect to the following: the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to cure the conditions proximately related to the use of the product, as well as the other permanent and lasting severe personal injuries.

142. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Ventralex ST Mesh, which deprived Plaintiff and her implanting physician of vitally necessary information with which to make a fully informed decision about whether to use the product.

143. At all material times, Defendants also knew and recklessly and/or intentionally disregarded the fact that their product can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatments. But Defendants recklessly failed to advise the medical community and the general public, including Plaintiffs, of that fact.

144. At all material times, Defendants intentionally misstated and misrepresented data; and they continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the Ventralex ST Mesh.

145. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Ventralex ST Mesh, with its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of the complications and side effects.

146. When Plaintiff JOLENE GENTLEMAN was implanted with the Ventralex ST Mesh and since then, Defendants have known the product was defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell Ventralex ST Mesh so as to maximize sales and profits at the expense of the health and safety of

the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the product to members of the public, including Plaintiff.

147. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the product, so as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

148. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff JOLENE GENTLEMAN demands judgment against Defendants individually and jointly and severally. Plaintiff also requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff [name] demands judgment against Defendants, individually and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiff; permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

JURY TRIAL DEMANDED

ii. Restitution and disgorgement of Defendants' profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future costs of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff JOLENE GENTLEMAN hereby demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED this 9th day of August, 2018 at Anchorage, Alaska

LAW OFFICES OF DAVID HENDERSON
Attorney for Plaintiff Gentleman

s/ David Henderson
David Henderson #9806014